

**510(k) SUMMARY
FOR
SOMATOM Force**

APR 17 2014

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: November 21, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. General Information

Importer/Distributor:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:

2240869

Manufacturing Site:

SIEMENS AG, MEDICAL SOLUTIONS
Siemensstrasse 1
91301 Forchheim, GERMANY

Establishment Registration Number:

3004977335

2. Contact Person:

Mrs. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-1772 Fax: (610) 448-1778
Email: kimberly.mangum@siemens.com

3. Device Name and Classification

Product Name:	SOMATOM Force
Propriety Trade Name:	SOMATOM Force
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750

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Device Class: Class II
Product Code: 90JAK

Legally Marketed Predicate Devices

Trade Name: SOMATOM Definition Flash
510(k)#: K21072
Clearance Date: May 08, 2012
Classification Name: System, X-Ray, Tomography, Computed
Classification Panel: Radiology
Classification Regulation: 21 CFR § 892.1750
Device Class: II
Product Code: 90 JAK

4. Substantial Equivalence:

Siemens SOMATOM Force is substantially equivalent to the following medical devices in commercial distribution:

<i>Predicate Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>
SOMATOM Definition Flash	K121072	May 08, 2012

5. Device Description:

The SOMATOM Force is a whole body X-ray Computed Tomography System which features two continuously rotating tube-detector systems and functions according to the fan beam principle. The SOMATOM Force produces CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The computer system delivered with the CT scanner is able to run the post processing applications optionally.

6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

The SOMATOM Force is comparable in indications for use, design, material, functionality, technology, energy source and is considered substantially equivalent to the predicate device SOMATOM Definition Flash (K121072, clearance date May 08, 2012).

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The differences between the legally marketed predicate device and the SOMATOM Force are as follows:

Property	SOMATOM Force	SOMATOM Definition Flash
X-Ray Assembly Tube	2 × Vectron	2 × Straton MX P
Generator Power (max.)	120 kW/120 kW	100 kW/100 kW
Number of Detector Rows	96/96	64/64
Maximum Number of slices/rotation	192/192	128/128
Number of measuring channels in detector	1840/1280	1472/960
Beam Hardening Correction	Iterative Beam Hardening Correction (IBHC)	Posterior Fossa Optimization (PFO)

The SOMATOM Force is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission.

The SOMATOM Force also supports Iterative Beam Hardening Correction (IBHC). The Iterative Beam Hardening Correction (IBHC) feature is an extension of the Posterior Fossa Optimization (PFO) feature. The PFO feature was cleared as part of the SOMATOM Definition Flash (K082220, clearance date October 10, 2008) and part of the predicate device SOMATOM Definition Flash (K121072, clearance date May 08, 2012).

IBHC is a raw data based beam hardening correction method designed to improve image quality. IBHC uses 3D forward projection, and an additional two-compartment iodine/water model to reduce beam hardening artifacts while maintaining anatomical structures.

The intended use, materials, energy source, and fundamental scientific technology are similar to the predicate device; therefore Siemens believes that they are substantially equivalent to the predicate device.

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7. Nonclinical Testing:

The SOMATOM Force is designed to fulfill the requirements of following safety and performance standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
2-156	Biocomp	<u>Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process</u>	10993-1:2009	01/15/2013	AAMI ANSI ISO
12-120	Radiology	<u>Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography - Ed. 2.1</u>	60601-2-44 (2002-11):	09/09/2008	IEC
12-126	Radiology	<u>Medical electrical equipment - Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis - Ed. 1.0</u>	60601-2-28: 1993	10/31/2005	IEC
12-127	Radiology	<u>Medical electrical equipment - Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment - Ed. 1.0</u>	60601-2-32: 1994	10/31/2005	IEC
12-199	Radiology	<u>Medical electrical equipment - Part 1-3: General requirements for basic safety 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment</u>	60601-1-3 First edition 1994-07	09/08/2009	IEC
12-204	Radiology	<u>Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis</u>	60601-2-28 Edition 2.0 2010-03	08/05/2013	IEC
12-210	Radiology	<u>Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment</u>	60601-1-3 Edition 2.0 2008-01	08/05/2013	IEC

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Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
12-223	Radiology	<u>Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment</u> <u>CORRIGENDUM 1</u>	61223-3-5 (First edition 2004)	03/18/2011	IEC
12-225	Radiology	Computed Tomography Dose Check	XR 25	03/18/2011	NEMA
12-226	Radiology	<u>Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment</u>	61223-2-6 Second Edition 2006-11	02/28/2011	IEC
12-238	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.18	03/16/2012	NEMA
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-27	General	<u>Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems</u>	60601-1-1:2000	09/08/2009	IEC
5-4	General	<u>Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995</u>	60601-1	10/31/2005	IEC
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO
5-41	General	Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4:2000 Consol. Ed. 1.1	09/08/2009	IEC
5-54	General	<u>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)</u>	60601-1-2:2007	08/05/2013	AAMI ANSI IEC

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) and phantom testing were conducted for the SOMATOM Force during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

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The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

8. Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data. The images delivered by the system can be used by a trained physician as an aid in diagnosis.

9. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that the SOMATOM Force does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Siemens Medical Solutions USA, Inc.
% Kimberly Mangum
51 Valley Stream Pkwy.
MALVERN PA 19355

Re: K133589/S002

Trade/Device Name: SOMATOM Force
Regulation Number: 21 CFR 892.1750
Regulation Name: System, X-Ray, Tomography, Computed
Regulatory Class: II
Product Code: JAK
Dated: March 14, 2014
Received: March 18, 2014

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over a rectangular grid pattern.

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K133589

Device Name

SOMATOM Force

Indications for Use (Describe)

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data. The images delivered by the system can be used by a trained physician as an aid in diagnosis.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

